

FORM PTO-1390 (Modified)
(REV 10-95)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

10/009138

INTERNATIONAL APPLICATION NO.

INTERNATIONAL FILING DATE

PRIORITY DATE CLAIMED

PCT/IB97/00887

17 July 1997

25 July 1996

TITLE OF INVENTION

A FLEXIBLE ANNULAR STAPLER FOR CLOSED SURGERY OF HOLLOW ORGANS

APPLICANT(S) FOR DO/EO/US

PAVIV TOSSEDANO

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
 - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ A copy of the International Search Report (PCT/ISA/210).
8. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 18 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
A **SECOND** or **SUBSEQUENT** preliminary amendment.
16. ☐ A substitute specification.
17. ☐ A change of power of attorney and/or address letter.
18. ☐ Certificate of Mailing by Express Mail
19. ☐ Other items or information:

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.101)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
10/009138		PCT/IB97/00887			
20. The following fees are submitted:				CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :					
<input type="checkbox"/> Search Report has been prepared by the EPO or JPO \$ 890.00					
<input checked="" type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) \$ 710.00					
<input type="checkbox"/> No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) \$ 740.00					
<input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$ 1,040.00					
<input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) \$ 100.00					
ENTER APPROPRIATE BASIC FEE AMOUNT =				\$ 710.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).				\$ 130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	15-20 =	< 0	x \$18.00	\$ 0.00	
Independent claims	3-3 =	0	x \$ 84.00	\$ 0.00	
Multiple Dependent Claims (check if applicable).			<input type="checkbox"/>	\$0.00	
TOTAL OF ABOVE CALCULATIONS =				\$ 840.00	
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable).			<input checked="" type="checkbox"/>	\$ 420.00	
SUBTOTAL =				\$ 420.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).				\$0.00	
TOTAL NATIONAL FEE =				\$ 420.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable).			<input type="checkbox"/>	\$0.00	
TOTAL FEES ENCLOSED =				\$ 420.00	
				Amount to be refunded	\$
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<input checked="" type="checkbox"/> Payment of the amount of \$ 420 by money-order. Copy of the mandater receipt is attached.					
<input type="checkbox"/> Please charge my Deposit Account No. in the amount of to cover the above fees. A duplicate copy of this sheet is enclosed.					
<input type="checkbox"/> The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. A duplicate copy of this sheet is enclosed.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO:					
TOLEDANO Haviv C/O METZMAN David 693 Downing Street Teaneck - NJ 07666			SIGNATURE Haviv Toledano (Applicant/Inventor) NAME November 10, 2001 DATE		

JC19 Rec'd PCT/PTO 26 NOV 2001
REMARK OFFICE

- a) providing a flexible annular stapler having two round jaws;
- b) inserting said jaws into a first one of the two parts and advancing said jaws to where one jaw is inside the first part and the other jaw is inside the second one of the two parts, each jaw being substantially near the respective plane;

- c) for each of the two parts, shrinking the opening so as to form an at least partially closed butt that encloses the respective one of said jaws, pressing the tissue surrounding the opening to form a pair of adjoining lips and stapling said lips together by means of a linear stapler, and
 - d) operating said annular stapler so as to pull the two said butts together and essentially combine the two annular areas into a combined annular area, to staple the two organs or segments to each other over said combined annular area and to cut away portions of said butts that are central to said combined annular area.
- v) Please replace pages 37-40 by the replacement pages submitted herewith.

REMARKS

The specification before the Examiner is a divisional application following the restriction/election required under 35 U.S.C 121 by the Examiner on June 21,2000 for Application Ser. No. 09/214,039

The claims before the Examiner are directed toward specific surgical methods, using a flexible annular stapler (to the present applicant), for joining together two parts of hollow tubular organs, in closed surgery (i.e, Laparoscopic surgery) conditions.

Examination of the present application in view of the amendments and remarks following is respectfully requested.

- i) Claims 1-9 and 17 were allowed in US patent application serial No. 08/687,315 (now US patent No. 5,855,312)
- ii) Claims 10-16 and 18-22 were cancelled and replaced by claims 41-66. These claims (41-66) were subject to Continued Prosecution Application (of US Patent Application Ser. No. 09/214,039) and were allowed in US Patent Application Serial No. 09/846,362 now pending.
- iii) Claims 25-26 were cancelled concomitantly with the above amended independent claim 23 in response to the written /opinion mailed 21 April 98.
- iv) The amended independent claim 23 here above and its dependent claims 24 and 27 were deemed to meet the criteria of Novelty, Inventive step and Industrial Applicability in the International Preliminary Examination Report (PCT/IB97/00887) mailed 06 Jan. 99 by the US Authority.
- v) Submitted herewith are replacement pages 37-40 in which amendments have been effected to the other claims of the present specification.

More specifically, independent claim 28, has been amended to recite that the steps of the method enumerated therein are performed under conditions of closed surgery (i.e. laparoscopic surgery). Its respective claim 30, previously reciting such limitation has been cancelled . Claim 32 now depends from claim 31 instead of claim 28.

Further, independent claims 28 and 35, describing each a surgical method, have been amended in order to clarify and emphasize that the initially detached jaw(s) is/are introduced into the body cavity (abdomen/thorax) through a suitable opening ("hole") created on patient's intact body wall. A next step requiring attachment of the detached jaw, is being done (by snap-coupling) inside the body cavity (by another commercially available surgical tool such as a laparoscopic grasper).

Furthermore, independent claim 35 has also been amended in order to clarify and emphasize the originality of the surgical method described in. By that method, the **flexible tubular body** of the **annular stapler, virgin of his two jaws** is inserted into the body cavity (abdomen/thorax) through a "classic" trocar port [of weak nominal diameter (<10mm)] for laparoscopic surgery. The jaws are in a next step, snap-fitted to it (-as said above-) **inside** the body cavity.

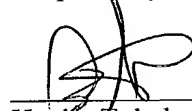
Amended independent claims 28 and 35 now feature language which makes it absolutely clear that the methods of the present specification are novel and inventive and not anticipated by KURAMOTO et al. (US 5,395,030) as stated on the International Preliminary Examination Report (PCT/IB 97/00887) mailed 06 Jan.99

Support for the amendments can be found in the specification. Specifically, support for the amendments of independent claim 28 can be found in the specification in Fig. 13 and on page 26, line 11 – page 27, line 7.

Support for the amendments of claim 35 can be found in the specification in Fig. 16 and on page 30, line 10 – page 31, line 12.

In view of the above amendments and remarks it is respectfully submitted that this specification is in condition for allowance.

Respectfully Submitted,



Haviv Toledano

Applicant/Inventor

Date: 10 November 2001

27. The method of claim 23, wherein at least one additional surgical operation is performed between steps (a) and (d).

28. A method for joining two parts of hollow organs over an annular area defined on a plane in each of said two organs or segments, under conditions of closed surgery on a patient, the method comprising the steps of-

- (a) providing a flexible annular stapler having a flexible body, two round jaws and a flexible cable sliceable through said body and through a first one of said jaws and having an end protrudable from said first jaw, said second one of said jaws being attachable to said end of said cable, said second jaw being initially detached;
- (b) inserting said first one of said jaws into a first one of the two parts of hollow organs, advancing said first jaw to where it is inside the first part near the respective plane and causing said end of said cable to protrude from said first part;
- (c) introducing said second jaw into a body cavity through the patient's body wall and attaching it in the inside of said body cavity to said end of said cable;
- (d) having said second jaw inside the second one of the two parts of hollow organs and having each of the two parts form an at least partially closed butt at or near the respective plane, said butt enclosing the respective one of said jaws; and
- (e) operating said annular stapler so as to pull said two butts together, to staple the two organs or segments to each other over the annular areas and to cut away portions of said butts that are central to the annular area.

29. The method of claim 28, wherein said inserting is effected through a natural opening of the patient's body.

31. The method of claim 28, wherein at least one of the two parts of hollow organs has an opening through its respective plane essentially inside the respective annular area, the method further comprising, for each of the two parts, the step of shrinking the opening so as to form an at least partially closed butt.

32. The method of claim 31, wherein said shrinking includes, with respect to each of the two parts, pressing the tissue surrounding the opening to form a pair of adjoining lips and stapling said lips together by means of a linear stapler.

33. The method of claim 28, further comprising, prior to step (c), the step of causing said end of said cable to protrude into the second one of the two parts of hollow organs.

34. The method of claim 28, wherein at least one surgical operation is performed between steps (a) and (e).

35. A method for joining two parts of hollow organs over an annular area defined on a plane in each of the two parts, under conditions of closed surgery performed on a patient, the method comprising the steps of –

- (a) providing a flexible annular stapler having a flexible body, two round jaws and a flexible cable slidable through said body and through a first one of said jaws and having an end protrudable from said first jaw, the first one of said jaws being attachable to said body and the second one of said jaws being attachable to said end of said cable, both of said jaws being initially detached;
- (b) inserting said flexible body through a suitable trocar port in the patient's body wall;
- (c) introducing said first jaw into a body cavity through the patient's body wall and attaching it in the inside of said body cavity to said flexible body;
- (d) introducing said second jaw into a body cavity through the patient's body wall and attaching it in the inside of said body cavity to said end of said cable;
- (e) having said first jaw inside the first one, and said second jaw inside the second one, of the two parts of hollow organs and having each of the two parts form an at least partially closed butt at or near the respective plane, said butt enclosing the respective one of said jaws; and
- (f) operating said annular stapler so as to pull said two butts together, to staple the two organs or segments to each other over an annular area and to cut away portions of said butts that are central to said annular area.

36. The method of claim 35, wherein at least one of the two parts of hollow organs has an opening through its respective plane essentially inside the respective annular area, the method

further comprising, for each part having an opening, the step of shrinking the opening so as to form an at least partially closed butt.

37. The method of claim 36, wherein said shrinking includes pressing the tissue surrounding the opening to form a pair of adjoining lips and stapling said lips together by means of a linear stapler.

38. The method of claim 35, further comprising, prior to step (c), the step of having said flexible body protrude into one of the two parts.

39. The method of claim 35, further comprising, prior to step (d), the step of having said end of said cable protrude into one of the two parts.

40. The method of claim 35, wherein at least one surgical operation is performed between steps (a) and (f).

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